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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/336,392 | 06/18/1999 | TERRENCE R. GREEN | 25658-0002 | 7579 |

25213 7590 12/18/2002

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| EXAMINER |
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DEWITTY, ROBERT M

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/336,392

Applicant(s)

GREEN ET AL.

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61, 62 and 64-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61, 62, 64-69, 73-75, 92, 93, 95, 96, 99-104, and 109-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 61-62, 64-111 are pending in the instant application. Claims 61, 62, 64-69, 73-75, 92, 93, 95, 96, 99-104, and 109-11 are drawn to the elected species.

Acknowledgement is made of Applicant's response filed 10/24/02.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 61, 62, 64-69, 73-75, 92, 93, 95, 96, 99-104, and 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (U.S. Pat. No. 4,576,817) further in view of Karns (U.S. Pat. No. 1,867,222).

Montgomery teaches enzymatic absorbent materials for body contact applications. The materials contain serum-activated oxidoreductase enzyme for producing hydrogen peroxide (Abstract). A suitable oxidoreductase enzyme is Glucose Oxidase (Table A). The material can also contain iodine along with the enzyme (claim 13). A second enzyme provided with the enzymatic material can interact with hydrogen peroxide and an oxygen-accepting anion. Oxygen-accepting anions in serum include iodide ions (col. 3, line 55-col. 4, line 5). The contraceptive flexible foam pad can be obtained by incorporating spermicidal composition in the invention (col. 8, lines 20-22). Montgomery teaches that the invention can be practiced through gauze bandaging alone or secured to adhesive strips and feminine hygiene absorbent pads and tampons, as well as other internally utilizable body contact devices having high absorbency

Art Unit: 1616

characteristics (col. 3, lines 2-8). The enzymes may be advantageously encapsulated. The encapsulating material can be composed of a water soluble polymer or a polymer permeable to a substrate. An example of encapsulating material is carboxymethylcellulose (col. 4, lines 61-68).

Karns teaches materials for making dressings. It is taught that elemental iodine would be an excellent antiseptic agent, but the iodine will lose some of its antiseptic power (col. 1, lines 6-30). To address these problems, Karns invention consists of a gauze that will release free iodine to serve the antiseptic purpose. To accomplish this, a gauze is impregnated with an iodine-containing material and a material capable of releasing iodine from such iodine containing material. The iodine-releasing material can be an iodide such as sodium iodide, potassium iodide, or barium iodide. The oxidizing material can be metallic iodates, such as calcium and potassium iodate.

One with ordinary skill in the art would have been motivated to utilize the teachings of Karns in Montgomery because the use of an iodine-releasing material and an oxidizing material such as iodate would deliver the benefits of iodine (as an excellent antiseptic agent) while avoiding the drawbacks (lose of power). Further, one with ordinary skill would have known that such a composition would be suitable for internal body contact (as taught by Montgomery).

Response to Arguments

2. Based on Applicant's amendments and response, the previous rejection under 35 U.S.C. 102 is withdrawn.

Art Unit: 1616

3. Applicant's arguments have been fully considered but they are not persuasive. Applicant asserts that Montgomery et al. does not teach an implantable anti-infective device. However, Montgomery clearly teaches the invention can be used for internally utilizable body contact devices. Whereas Examples II and III teach instances different from the instant invention, Montgomery clearly teaches that incorporation of enzyme into a fiber and foam. Further, Montgomery teaches use of an encapsulating material such as carboxymethylcellulose.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

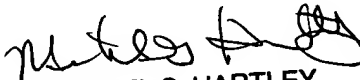
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
December 13, 2002


MICHAEL G. HARTLEY
PRIMARY EXAMINER